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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,304	02/08/2005	Ira Sanders	SAND3.0-002PCT/US	6448

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OMRI M. BEHR
325 PIERSON AVENUE
EDISON, NJ 08837-3123

EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/524,304	SANDERS ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34,45-49 and 56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34,45-49 and 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of holocrin glands as the subgenus and sebaceous glands as the species in the reply and amendment filed on May 23, 2006 is acknowledged. In the amendment, claims 45 and 46 have been amended and a new claim 56 has been added. The traversal is on the ground(s) that the claims are properly linked as being related to a use of botulinum toxin, and claim 1 is generic to claims 1-34. Applicants' response has been considered, and the arguments are found persuasive, thus the requirement for species election is withdrawn. Therefore, claims 1-34, 45-49 and 56 are examined.

Informalities

The disclosure is objected to because of the following informalities:

2. The specification recites a web address (e.g., page 14, line 33) which is impermissible. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-34, 45-49 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 1-34, 45-49 and 56 are indefinite because the claims lack an essential step in the method of controlling the secretions from glands or a method of smoothing fine wrinkles in the

skin and decreasing the skin pore size of a subject in need of same. The omitted step is the outcome of the treatment. Claims 2-34 and 45-49 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

5. Claims 1-34 are indefinite because of the use of the term "whose level of glandular secretion is greater than desirable". The term cited renders the claim indefinite, it is not clear what level of glandular secretion is "desirable", since the specification does not define it. Claims 2-34 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

6. Claim 3 recites the limitation "the conditions" in line 1. There is insufficient antecedent basis for this limitation in the claim.

7. Claims 29-34 are indefinite because of the use of the term "the botulinum toxin comprises botulinum toxin B". The term cited renders the claim indefinite, it is not clear how the botulinum toxin, which is a compound, can comprise another compound, i.e., botulinum toxin B.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002

do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-6, 8-11, 14-19, 22-34, 45-47, 49 and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Suskine *et al.* (US 2005/0074466, priority date July27, 2001).

Suskine *et al.* teach the use of botulinum toxin (i.e., serotype A, B, C, D, E, F, G) to treat acne, which the pathology centers on the pilosebaceous follicle comprising the sebaceous gland, the follicle (pore) and the vellus hair (paragraph [0005]), and the treatment may be repeated periodically to inhibit the recurrence of acne, typically at intervals between about 3 months and about 6 months, preferably about once every 4 months (paragraph [0036]; claims 1-2, 26-34). For example, a female patient with severe cystic acne is injected intracutaneously with botulinum toxin A in her forehead, chin and cheek/nasolabial fold area approximately one every six months. After the treatment, she experienced a complete resolution of her acne, and the injections are spaced approximately 1.5 cm apart from one another, and the dose per injection site is about 2.5 U (Example 1; claim 3, 5, 8, 14, 15, 22, 23). Since the reference also teaches botulinum toxin

can be applied to the skin topically as a cream or in other forms (paragraph [0098]; claims 4 and 45), or can be injected intramuscularly (see claim 6 of US 2005/0074466; claim 9) or subcutaneously (see claim 5 of US 2005/0074466; claim 6), it would be obvious that botulinum toxin A would be injected intramuscularly or subcutaneously at the same sites using the same dosage as Example 1 (claims 10, 11, 16-19, 24 and 25). Since acne is a pathology of the skin pore, the treatment of patients having acne with topical administration, or subcutaneous or intracutaneous injection of botulinum toxin would smooth the fine wrinkles and decrease the skin pore size of the patients (claims 46, 47, 49 and 56). The term "cutaneous" is equivalent to "dermal", see page 11, line 31-32 of the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 1, 3, 5, 6, 9, 18, 19 and 28-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Brin *et al.* (US 2002/0094339; priority date: February 8, 2002).

Brin *et al.* teach a method of treating mammary gland disorders such as treating hyperplastic and/or hypertonic mammary gland cells by local administration (i.e., subdermal or intramuscular injection; paragraphs [0120], [0131]; Example 2) of an effective amount (i.e., 10^{-3} U/kg to 2000 U/kg, corresponding to 0.18 U to 1.2×10^5 U, assuming the average weight of a person is 60 kg) of a botulinum toxin (e.g., serotype A, B, C, D, E, F, or G) to a hyperplastic or hypertonic mammary gland tissue, thereby reducing a secretion from hyperplastic or hypertonic mammary gland tissue (paragraphs [0104] and [0110]; claims 1, 3, 5, 6, 9, 18, 19, 28-34).

10. Claims 46 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Letessier (J. Dermatol. Treat. 10, 31-36 (1999)).

Letessier teaches injection of an effective amount of botulinum toxin A in the treatment of wrinkles, e.g., periorbicular wrinkles (pages 32-35; claims 46 and 56).

Conclusion

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner

CHIH-MIN KAM
PATENT EXAMINER

CMK
June 23, 2006